

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JUN 3 0 2017

OFFICE OF CONGRESSIONAL AND INTERGOVERNMENTAL RELATIONS

The Honorable Pat Roberts Chairman Committee on Agriculture, Nutrition and Forestry United States Senate Washington, D.C. 20510

Dear Chairman Roberts:

Enclosed please find the U.S. Environmental Protection Agency's responses to the committee's Questions for the Record following the May 11, 2017, hearing on "Pesticide Registration under the Federal Insecticide, Fungicide, and Rodenticide Act: Providing Stakeholders with Certainty through the Pesticide Registration Improvement Act."

If you have further questions, please contact me or your staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at kaiser.sven-crik@epa.gov or (202) 566-2753.

Troy M. Lyons
Associate Administrator

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 3 0 2017

OFFICE OF CONGRESSIONAL AND INTERGOVERNMENTAL RELATIONS

The Honorable Debbie Stabenow Ranking Member Committee on Agriculture, Nutrition and Forestry United States Senate Washington, D.C. 20510

Dear Senator Stabenow:

Enclosed please find the U.S. Environmental Protection Agency's responses to the committee's Questions for the Record following the May 11, 2017, hearing on "Pesticide Registration under the Federal Insecticide, Fungicide, and Rodenticide Act: Providing Stakeholders with Certainty through the Pesticide Registration Improvement Act."

If you have further questions, please contact me or your staff may contact Sven-Erik Kaiser in the EPA's Office of Congressional and Intergovernmental Relations at kaiser.sven-erik@epa.gov or (202) 566-2753.

Sincerely,

Troy M. Lyo

Associate Administrator

Enclosure

Senate Committee on Agriculture, Nutrition & Forestry

Pesticide Registration under the Federal Insecticide, Fungicide, and Rodenticide Act:
Providing Stakeholders with Certainty through the Pesticide Registration
Improvement Act
May 11, 2017

Questions for Mr. Rick Keigwin

Chairman Pat Roberts (R-KS)

Roberts 1. Please describe to us EPA's role regarding endangered species under FIFRA, including EPA's ecological risk assessment. Are significant agency resources dedicated to this type of analysis?

EPA Response. Before the EPA may register a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the applicant must show, among other things, that using the pesticide according to label specifications "will not generally cause unreasonable adverse effects on the environment." FIFRA defines environment as "water, air, land, and all plants and man and other animals living therein and the interrelationships which exist among these." The EPA evaluates the impacts of pesticides to all animal and plant species as part of ecological risk assessments that support decision making under the FIFRA standard of "no unreasonable adverse effects on the environment."

The application of the EPA's pesticide ecological risk assessment methods to all plant and animal species (except for five pilot projects discussed below) is described in a document called the Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, Environmental Protection Agency Endangered and Threatened Species Effects Determinations (Overview Document, 2004). Although the Overview Document is consistent with agency-wide ecological risk assessment guidance, based on available data sources, and supportive of pesticide regulatory decisions under FIFRA, the EPA, the U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS), collectively called "the Services", had historically been unable to reach agreement regarding application of the scientific methods described in the Overview Document to endangered and threatened species (collectively referred to as listed species) assessments conducted to support consultations under Section 7 of the Endangered Species Act (ESA). Under section 7(a)(2) of the ESA, the EPA must ensure that agency actions taken under FIFRA are not likely to jeopardize the continued existence of any ESA-listed species or destroy or adversely modify critical habitat.

As a result of the agencies' disagreements and numerous associated lawsuits against the EPA and the Services for failure to meet ESA obligations, the EPA, the Services, and the U.S. Department of Agriculture (USDA) sought out the advice of the National Academy of Sciences (NAS) to provide recommendations on how to assess the risk of pesticides to ESA-listed species and critical habitat. In an April 2013 report, NAS provided recommendations to the EPA, the

Services, and USDA on a common interagency approach for ESA pesticide consultations. Since release of the NAS report in 2013, the EPA has been working with the Services and with USDA as an invited participant, to develop shared interim scientific approaches in the context of national-level listed species risk assessments for five pilot chemicals (chlorpyrifos, diazinon, malathion, carbaryl, and methomyl) currently undergoing registration review.

The EPA has employed a three pronged strategy that is intended to protect listed species and critical habitat by focusing resources on areas where we can achieve the most protections. First, the EPA is focusing the majority of its ESA consultation work through registration review.

Second, the EPA intends to complete endangered species assessments for new herbicide tolerant crops. In order to maximize resources, these initial registrations will not be nationwide in scope, and to the extent practical, will focus on situations where the EPA can make "no effect" decisions for ESA-listed species and critical habitat.

Third, the EPA will provide information that compares the potential hazards of new active ingredients to already registered pesticides with similar modes of toxicity and the same use patterns to allow comparison of the relative toxicity of new chemicals to available alternatives. EPA resources needed to conduct ecological risk assessments in support of FIFRA regulatory decisions as described in the three pronged strategy above are estimated at approximately 55 to 60 FTE per year, depending upon the number of submissions received each year under the Pesticide Registration Improvement Act (PRIA) and the complexity of any risk assessments conducted as part of the registration review program.

Roberts 2. Under the Endangered Species Act, the EPA is charged with examining their actions to regulate pesticides. If a pesticide "may affect and is likely to adversely affect" a listed species, the U.S. Fish and Wildlife Service and the National Marine Fisheries Service become involved in this regulatory process through formal consultation with the expert agency, here EPA. The Services then issue Biological Opinions providing documentation regarding whether a pesticide's use would jeopardize listed species or destroy or adversely modify critical habitat. Do the Services provide EPA with the best scientific and commercial data available in these processes? Does EPA have satisfactory access to this data, including any modeling done by the Services? In what ways could the Services improve their Biological Opinions provided to EPA, or towards the consultation process generally? Is there sufficient transparency in these processes?

EPA Response: Section 7(a)(2) of the ESA requires that Federal agencies, including EPA, "in consultation with and with the assistance of the Secretary," ensure their discretionary actions do not likely to jeopardize the continued existence of any endangered or threatened species, or result in the destruction or adverse modification of critical habitat. Regulations at 50 CFR 402 set forth procedures for consultations between the Services and Federal agencies on actions that may affect listed species or designated critical habitat. Pursuant to these regulations, if an action is likely to adversely affect listed species or critical habitat, formal consultation is required. Formal consultation commences with the Federal agency's written request for consultation and concludes with the appropriate Service's issuance of a biological opinion. Federal agencies requesting

¹ https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides

formal consultation are required to provide the Services with the best scientific and commercial data available or which can be obtained during the consultation. The Services use that information and any otherwise available information during consultation and the preparation of the biological opinion.

The Services assist Federal agencies in carrying out their section 7(a)(2) responsibilities, in part, by providing technical assistance. For example, for the ongoing pesticide consultations on the five pilot chemicals initiated after release of the 2013 NAS report, the Services assisted EPA by providing us with geospatial data depicting the occurrence of listed species and critical habitat. Such information is critical in establishing the overlap of species ranges with the areas of expected pesticide use. The spatial location data were obtained from the Services' field offices and provided to the EPA in varied levels of resolution, ranging from county to sub-county data. While this information is considered "best available data," the agencies have acknowledged the need to further refine the maps for future consultations.

Consistent with the consultation regulations, the Services typically rely on the EPA's biological evaluations for the exposure modeling and toxicity data cited in their Biological Opinions. NMFS relied on the biological evaluations as well as a peer reviewed salmon population model in their Biological Opinions. The EPA supports the use of population models in listed species assessments for pesticides, and is working with the Services on the development of those models.

Since the NAS report was released in 2013, the EPA has been working collaboratively with the Services on interim methods related to the final step of the ESA consultation process for pesticides in order to complete the first five pilot consultations using those methods. Due to the complexity of the consultations and the large number of species and critical habitats being assessed, the agencies are working to establish agreements intended to provide greater efficiencies and transparency to the consultation process.

The agencies are using the process described in the 2013 paper entitled, "Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives" to ensure opportunities for stakeholder engagement and public comment. As part of this process, once received, EPA intends to make the Services' draft Biological Opinions available for public comment.

Roberts 3. How much does it cost EPA from start to finish to complete a consultation with the Services? Please include any full time equivalent (FTE) estimate as well for the agency.

EPA Response: To date, the EPA has completed formal consultation with the Services, including implementation of the mitigation identified in the biological opinions, on a small number of pesticides, all of which were limited in terms of geographic scope and the number of species subject to consultation.

² Available at www.regulations.gov in docket: EPA-HQ-OPP-2012-0442.

The EPA completed a formal consultation with FWS on the rodenticide products, Rozol and Kaput prairie dog baits, in a 10 state area. Consultations with NMFS on listed Pacific Northwest salmon have also occurred for 32 chemicals in seven different biological opinions, although one biological opinion covering three chemicals was remanded. Mitigation recommended in one of the biological opinions, thiobencarb, have been implemented.

Pesticide consultation costs are supported with FTEs. However, data to support an accurate estimation of costs associated with nationwide pesticide consultations are not yet available because these consultations are ongoing and not yet complete. Since release of the NAS report in 2013, the agencies have worked with litigants to align ESA related lawsuits so that the agencies can focus on national level consultations on all ESA-listed species rather than the focus on single species, or a small subset of species in smaller geographical areas. As a result, the EPA and the Services agreed to complete nationwide pesticide consultations for five pilot chemicals (chlorpyrifos, diazinon, malathion, carbaryl, and methomyl) based on shared interim methods.

Since the EPA began the nationwide pesticide consultation work in fiscal year 2014, the EPA has expended approximately 6 FTE in FY 2014, 10 FTE in FY 2015, 10 FTE in FY 2016, and 5 FTE in the first half of FY 2017, in staff resources on pesticide consultations under the ESA. The work completed in fiscal years 2014 through mid-2017 has been largely focused on the development of the EPA's biological evaluations for the five pilot chemicals. These estimated costs do not include the EPA review of the Service's draft Biological Opinions and coordination with external stakeholders to implement any necessary label changes based on the conclusions of the final Biological Opinions since these steps have not yet occurred. Since the agencies have not yet completed a nationwide pesticide consultation following release of the 2013 NAS report, a comprehensive estimation of the total costs of pesticide consultation is not available.

Roberts 4. "PRIA 4," which passed the House in a bipartisan manner on the suspension calendar, contains a reauthorization provision for 7 years. Can you please walk us through a timeline that illustrates how this 7-years will be used towards the registration of pesticides?

EPA Response: The Pesticide Registration Improvement Extension Act of 2017 (PRIA 4) extends the authorization of the fee for service framework under PRIA for an additional seven years. During that time, applicants who submit applications under one of the PRIA categories and pay the required fee have the certainty that there is an established time frame for the EPA to review and provide its decision on that application. The EPA will review and provide decisions on all applications received over those seven years in accordance with the time frames and provisions specified in PRIA.

PRIA 4 also establishes funding to support good laboratory practice (GLP) inspections and to develop product performance guidance. The EPA will utilize the funds set aside from maintenance fees for those activities, and in the case of the product performance activities, will adhere to the deliverable schedule specified in the bill. Worker protection, partnership grants, and pesticide safety education activities will continue, using the funds specified for those activities. The EPA will provide an annual report each fiscal year providing the information required in the reporting requirements.

Roberts 5. The Texas State Department of Agriculture submitted a request to EPA for a Section 18 exemption for the emergency use of sulfoxaflor to deal with the Asian Citrus Psyllid, the vector for Huanglongbing (HLB or citrus greening). I understand EPA recently rejected this request. What impacts will this decision have on citrus growers in Texas and how will this impact the citrus industry more broadly? What recourse is available, if any, for EPA to reconsider this request?

EPA Response: The EPA conducted an initial review of the Texas Department of Agriculture's (TDA) FIFRA section 18 emergency exemption request for the use of sulfoxaflor on citrus to control the Asian Citrus Psyllid (ACP), and provided feedback to TDA about its application. However, no regulatory decision has been made on this request. The agency is currently in discussion with TDA and their extension expert to carefully assess the pest situation and the requirements for an emergency clearance under FIFRA.

As you may know, the regulations that establish the conditions for emergency approval state that the EPA must conclude that "no effective pesticides are available for control of the pest." The EPA approved emergency use of another pesticide, clothianidin, for this purpose to TDA on February 7, 2017. The agency is aware of the devastating impact ACP can have on citrus product. As a result, the EPA is carefully assessing the availability of sufficient control measures with TDA to evaluate if a critical pest management gap exists. Emergency requests may also be reconsidered or resubmitted at any time. The EPA is committed to supporting producers, researchers and industry stakeholders in their efforts to help mitigate this difficult disease.

Roberts 6. In your testimony you discuss an initiative launched by Administrator Pruitt-the "Back to Basics" agenda. Can you elaborate further on what EPA hopes to achieve through this effort, who are the stakeholders, and what action items should Congress anticipate from this?

EPA Response: The EPA Administrator launched a "Back to Basics" agenda -- a formal plan to return the agency to its core mission of protecting the environment while engaging in cooperative federalism across a broad spectrum of interested parties. For example, as part of the administration's regulatory reform effort, the EPA held a public meeting in early May to garner feedback on pesticide registration issues. With more than 175 participants, this meeting, one of several regulatory reform meetings held by the EPA program offices, allowed regional, local, agricultural, and other pesticides stakeholders to share their views on pesticide regulatory development, reform initiatives, evolving public policy and program implementation issues. These meetings highlighted the Administrator's commitment to all Americans in returning common sense, as well as transparent and peer reviewed science, to the pesticide registration process. For more information on the Administrator's "Back to Basics" agenda, please visit: https://www.epa.gov/home/back-basics-agenda.

Ranking Member Debbie Stabenow (D-MI)

Stabenow 1. One of PRIA's roles is providing the agency with resources for training agricultural workers in the safe and appropriate application of pesticides. These PRIA resources complement important rules that the EPA recently promulgated in this arena, including the Worker Protection Standard (WPS) Rule and the Certified Pesticide Applicator (CPA) Rule. Last week, just hours after our hearing concluded, Administrator Pruitt delayed the implementation of those recently finalized rules. Why were the aforementioned rules' implementation dates delayed?

EPA Response: Regarding the Certified Pesticide Applicator (CPA) rule, the effective date is being extended to May 22, 2018, to give recently arrived agency officials the opportunity to conduct a substantive review of the rule in accordance with the Presidential directives as expressed in the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled "Regulatory Freeze Pending Review," and the principles identified in the April 25, 2017, Executive Order "Promoting Agriculture and Rural Prosperity in America." At this time, the EPA has only one Senate confirmed official, and the new administration has not had the time to adequately review the January 4, 2017, CPA rule. The extension to May 22, 2018, will prevent the confusion and disruption among the regulated community and stakeholders that would result if the CPA rule became effective (displacing the existing regulation) and then substantially revised or repealed as a result of administrative review. The 12 month extension also provides time for the EPA to consider revisions to the certification rule based on input received through the Regulatory Reform Agenda effort.

Regarding the Worker Protection Standard (WPS) rule, the EPA believes it is appropriate to extend the implementation of all revised provisions to the WPS to provide state lead pesticide agencies with additional time to successfully implement the rule changes. As a result, the EPA intends to initiate a rulemaking action in the near future to extend the WPS implementation dates. The EPA is also working with our state regulatory counterparts to identify what areas of the rule need clarification and additional guidance to ensure that the new requirements to protect farmworkers achieve their intended goal.

Stabenow 2. Stakeholders concerned with the WPS rule heard about the implementation delay through an agency letter responding to an association inquiry, instead of reading about it in the Federal Register. When will the WPS delay be published in the Federal Register?

EPA Response: The May 11, 2017, letter to the National Association of State Departments of Agriculture (NASDA) accepting their petition was informational and does not have the effect of regulation. The letter expressed EPA's general agreement with the petition and expressly stated that EPA "will soon begin the regulatory process to formally extend" the WPS compliance date. The EPA expects the notice of proposed rulemaking to be published in the Federal Register in the summer of 2017 and expects to have the rulemaking process completed in fall 2017.

Stabenow 3. The notice for the delay of the CPA rule included a public comment period lasting five business days. Why is the agency providing such a limited period for the public to comment on a rule that took several years to finalize?

EPA Response: The agency's implementation of the proposed delay in the effective date of the CPA rule with an abbreviated opportunity for public comment is based on the good cause exception in 5 U.S.C. 553(b)(B), in that providing additional time for public comment is impracticable, unnecessary and contrary to the public interest. The delay of the effective date until May 22, 2018, is necessary to give agency officials the opportunity for further review and consideration of the CPA rule, consistent with the memorandum of the Assistant to the President and Chief of Staff, dated January 20, 2017, and the principles identified in the April 25, 2017 Executive Order "Promoting Agriculture and Rural Prosperity in America." Given the imminence of the CPA rule effective date, allowing a longer period for comment on this delay would have been impractical, as well as contrary to the public interest in the orderly promulgation and implementation of regulations.

The 90 day comment period for the 2015 proposed rule, combined with the EPA's extensive stakeholder outreach, provided the EPA with robust public comment regarding the risks and benefits associated with the CPA rule. Since there was already public comment on the merits of the certification rule, the narrow issue of when the rule should become effective could reasonably be addressed in a short period of time. If the EPA had not shortened the comment period to five days, the January 4, 2017, certification rule would have gone into effect, displacing the earlier rule. It would have caused unnecessary confusion and disruption to certifying authorities, pesticide safety education programs, pesticide applicators and other stakeholders for the certification rule to go into effect and then potentially be substantially revised or repealed following a substantive review.

Stabenow 4. Would EPA consider extending the comment period on the CPA rule delay proposal to accommodate requests from interested stakeholders for more time?

EPA Response: As explained above, the 90 day comment period for the 2015 proposed rule, combined with the EPA's extensive stakeholder outreach, provided the EPA with robust public comment regarding the risks and benefits associated with the January 4, 2017, CPA rule. Since there was already a robust public comment on the merits of the CPA rule, the narrow issue of when the rule should become effective could reasonably be addressed in a short period of time. The EPA received more than 130 comments addressing the proposed delay in the effective date of the CPA rule from a variety of commenters including: state pesticide regulatory agencies; pesticide safety education programs; organizations representing state departments of agriculture, pesticide safety education programs, pesticide applicators, growers, pesticide manufacturers, and pesticide retailers; nongovernmental organizations representing a range of interests, including but not limited to farmworkers, environmental advocates, occupational or migrant health clinics and employment law; and many private citizens. On June 2, 2017, the EPA published a final rule extending the effective date of the CPA rule to May 22, 2018.

Stabenow 5. With regard to the WPS rule delay, EPA sent a letter to an outside stakeholder group on May 11, 2017 indicating that the agency was accepting the group's petition to delay implementation of the rule, despite EPA rejecting a nearly identical petition from the same group less than four months earlier. What caused EPA to change its position?

EPA Response: Although the length of delay requested in the two petitions was the same, their supporting rationales differed. The EPA did not agree with the first petition's contentions, among them the adequacy of enforcement guidance, educational materials and training resources.

Further discussions with state regulatory partners provided the EPA with a better understanding of the states' concerns about their ability to effectively implement the rule. The second petition presented a more compelling argument that the states need additional time and resources effectively implement the WPS revisions and provide compliance assistance to the regulated community. Accordingly, the EPA agreed with the petitioners and granted the request to extend the WPS compliance date.

Stabenow 6. Does EPA feel that the delay in the two rules contradicts the provisions provided by Congress in FIFRA, which requires EPA to ensure that pesticides sold and applied in the U.S. "will not generally cause unreasonable adverse effects on the environment?"

EPA Response: To protect human health and the environment from unreasonable adverse comments that might be caused by pesticides, the EPA developed and implemented a rigorous process for registering and re-evaluating pesticides. The specific risk reduction and mitigation measures that result from the registration and re-evaluation processes are implemented through individual pesticide product labeling. Regulations such as the WPS and CPA rules, as well as training, outreach and education, augment these efforts to prevent unreasonable adverse effects on the environment by reinforcing labeling requirement and establishing additional protections for agricultural workers, pesticide applicators, and other handlers and persons.

During the delays, the protections from the registration and re-evaluation processes will continue to be implemented, as will the previous versions of the WPS and CPA rules. The delays provide additional time for the EPA and the states to prepare for implementation. The memorandum of the Assistant to the President and Chief of Staff, dated January 20, 2017, directed the EPA to postpone the effective date for regulations that have not yet taken effect. This delay was for the purpose of the Administrator or his delegates to review questions of fact, law, and policy that the regulations raise. The requirements of the CPA rule would not have gone into effect immediately because states, tribes and federal agencies have three years to submit revised certification plans. For the CPA rule, the additional time provides the EPA an opportunity to work with states and others to develop checklists, guidance and tools to facilitate the development of revised certification plans. For the WPS extension of the compliance date, the additional time allows for the development of necessary guidance and documents and more time to educate the regulated community.

Even if the CPA rule had become effective on March 6, 2017, the procedures and standards used for certifying applicators would not have immediately changed. Regarding the WPS rule, while

the agency has expressed its intent to extend the compliance date for the revised provisions in the 2015 final rule, the rule as promulgated remains in effects until the agency takes the necessary statutorily required steps to extend the compliance date.

Stabenow 7. Does EPA feel that accepting a petition for delay of the WPS rule without publishing notice of the delay in the Federal Register runs afoul of the agency's responsibilities under the Administrative Procedures Act, particularly because some of the requirements of the rule in question have already been in effect for months?

EPA Response: The May 11, 2017, letter to NASDA accepting their petition was informational and does not have the effect of regulation. The letter expressed EPA's general agreement with the petition and expressly stated that EPA "will soon begin the regulatory process to formally extend" the WPS compliance date. The EPA expects the notice of proposed rulemaking to be published in the Federal Register in the summer of 2017 and expects to have the rulemaking process completed in fall 2017.

Stabenow 8. During the implementation delays, does EPA intend to change the substance of either the Certified Pesticide Applicator Rule or the Worker Protection Standards Rule?

EPA Response: The changes in the implementation dates do not directly affect the substance of these rules. The EPA is reviewing proposals to revise the CPA and WPS rules submitted in response to the Regulatory Reform process announced through Executive Order 13777.

Stabenow 9. If yes to the previous question, will such an effort be accompanied by a formal rulemaking and public notice and comment period, as is required for modifying rules that have already been finalized?

EPA Response: The EPA believes that substantive changes to the rules would require a formal rulemaking process that complies with the Administrative Procedure Act and the statutorily required rulemaking process, including public notification and comment.

Stabenow 10. Two weeks ago, President Trump and Administrator Pruitt abruptly dismissed several members of the EPA's Board of Scientific Counselors. As you mentioned during the hearing, the primary scientific advisory board at EPA relating to pesticides is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel. Does the administration plan future dismissals of scientists from the FIFRA scientific advisory panel?

EPA Response: The EPA does not have any plans to dismiss any current members of the FIFRA Scientific Advisory Panel (SAP). Consistent with standard practice for federal advisory committees, the EPA will consider extensions and normal rotation process when the terms of current FIFRA SAP members expire.

Regarding the EPA's Board of Scientific Counselors (BOSC), members serve three year terms that can be renewed once. On April 28, 2017, 13 members' terms expired. Four of these

members had served the maximum of two terms and could not be renewed for an additional term. The other nine members had served one term and were not renewed for a second term.

On May 25, 2017, the EPA published a federal register notice soliciting new members for the BOSC. The EPA anticipates that by late 2017, the BOSC will be reconstituted with expert scientists and engineers who will review and provide advice and recommendations on research under the EPA's Office of Research and Development. The individuals who have already served can reapply during the competitive nomination process.

Stabenow 11. Can you talk about the implications to the agency's mission of a potential future dismissal of scientists from the FIFRA panel?

EPA Response: The EPA does not have any plans to dismiss any current members of the FIFRA SAP. Consistent with standard practice for federal advisory committees, the EPA will consider extensions and normal rotation process when the terms of current FIFRA SAP members expire. The standing panel consists of seven members augmented with ad hoc experts for specific topics.

Stabenow 12. Would such a dismissal of scientists from the FIFRA panel conceivably cause a delay in pesticide approval and reregistration timelines?

EPA Response: The EPA does not have any plans to dismiss any current members of the FIFRA SAP. Consistent with standard practice for federal advisory committees, the EPA will consider extensions and normal rotation process when the terms of current FIFRA SAP members expire. A delay in scheduling peer review meetings can occur if a quorum of the standing panel falls below four members for any reason. The pesticide registration and registration review programs require the timely input of the FIFRA SAP on critical science issues to address safety for human health and the environment.

Stabenow 13. The majority of biopesticide active ingredients have historically met the safety standards of Section 408 of the Federal, Food, Drug and Cosmetic Act, resulting in exemptions from the requirement of tolerance for a food or animal feed. Please explain if the EPA's policy for granting tolerance exemptions has changed with respect to biopesticide active ingredients?

EPA Response: All tolerances and tolerance exemptions established by the EPA meet the safety standard under section 408 of the Federal, Food, Drug, and Cosmetic Act (FFDCA) of "reasonable certainty of no harm" from consumption of the food treated with the pesticide and from other non-occupational sources of exposure. It is the EPA's general practice to grant an exemption from the requirement of tolerance when no toxicological endpoints with adverse effects are observed in the data or literature provided in support of the registration application. Almost all biopesticides fall into this category. In instances where toxicological endpoints showing adverse effects are identified and risk assessment comparing exposure to those endpoints is required, the EPA has typically established numeric tolerances for residues in or on the treated commodity. This is consistent for all pesticides regulated by EPA including biopesticides, antimicrobials, and conventional pesticides.

Senator Patrick Leahy (D-VT)

Leahy 1. With the EPA's recently announced a one-year delay until the new regulations for the certification and training of pesticide applicators come into effect, the Administrator cited the need for giving the regulated community adequate time to come into compliance with the regulations. How does the EPA plan to actually support education, guidance and training efforts for our farmers and state lead agencies to assist them in understanding the requirements to ensure we are protecting children, farmworkers, and pesticide applicators from exposure to pesticides?

EPA Response: Even if the January 4, 2017, CPA rule had become effective on March 6, 2017, the procedures and standards used for certifying applicators would not have immediately changed. The CPA rule included an implementation schedule where the certifying authorities, e.g., states and federal agencies, would have up to three years to submit revised certification plans that conform to the revised standards with an additional two years for the EPA to review the plans and agree upon a timeline for the certifying authority to implement the plan.

The initial focus of the EPA's implementation efforts will be to develop the information and materials that certifying authorities need to determine what revisions are necessary to their certification plans and any associated laws, regulations and policies. The EPA held an intensive implementation course for state and tribal regulators on the CPA rule in April 2017, which identified or clarified many of the key implementation issues and the tools that certifying authorities need to move forward in revising state certification plans. During the next 12 months, the EPA plans to work with the certifying authorities, pesticide safety education programs, pesticide applicators and other stakeholders to develop checklists, guidance and tools to facilitate the development of revised certification plans and to discuss how to effectively implement the CPA rule.

Leahy 2. Will the President's Fiscal Year 2018 budget request include any funding increases to support this work to ensure that this rule can finally move forward next year?

EPA Response: The President's 2018 budget request does not include funding increases for CPA rule implementation.

Leahy 3. When the Pesticide Agricultural Worker Protection Standard Revisions were first proposed in 2014 and then finalized in 2015, they had been a long time coming and were the product of years of work by the EPA and received over 390,000 public comments. In the two years since the rule was initially finalized how has the EPA worked with the regulated community to educate and assist them with the transition to the updated requirements?

EPA Response: In 2016 and 2017, the EPA conducted extensive training for state, territorial and tribal regulatory agency program staff and inspectors and for pesticide safety educators, to develop a wide base of knowledge about the WPS revisions. The states and pesticide safety educators have more direct reach to the regulated community and do much of the educational

and compliance assistance activities. The EPA educated the regulated community and other stakeholders through webinars, meetings and discussions with national trade associations. During this time frame, the EPA revised the two key implementation documents: the WPS How to Comply Manual, which explains the WPS requirements to the regulated community (September 2016) and the WPS Inspection Manual (January 2017). The EPA also reviewed and approved pesticide safety training materials and train-the-trainer programs and has responded to hundreds of questions from states, the regulated community and other stakeholders. The following four other important implementation tools are being developed (with their anticipated completion date): (1) guidance on implementing the WPS respirator requirements (June 2017); (2) revised WPS pesticide safety poster (summer 2017); (3) an online train-the-trainer program (November 2017); and (4) a video version of WPS pesticide safety training for handlers (late 2017). Once these projects are complete, the regulated community will have the key tools it needs to comply with the WPS. As with any regulation, the EPA will continue to provide additional clarification and guidance as well as targeted tools like fact sheets over time.

Leahy 4. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) tasks the EPA's regional offices with overseeing states' pesticide-use programs and ensures that chemicals are actually used according to their label. In the past, some audits have found that different EPA regions were inconsistent in reporting or retaining records of issues discovered during reviews. How has the EPA strengthened its oversight to ensure adequate guidance and training on chemical use?

EPA Response: In response to the EPA Office of Inspector General Report 15-P-0156 titled, "EPA's Oversight of State Pesticides Inspections Need Improvement to Better Ensure Safeguards for Workers, Public and Environments are Enforced," the EPA strengthened its oversight to ensure adequate guidance and training on chemical use by the following actions:

- FIFRA Project Officer training a three day training presented in March 2015.
- FIFRA state grantee training a one day training presented in September 2016.